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Christopher B. Kilner, Esq.
Roberts Abokhair & Mardula, L.L.C.
Suite 1000
11800 Sunrise Valley Drive
Reston, VA 20191-5302

EXAMINER

SMITH, CAROLYN L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

DATE MAILED: 09/11/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,234

Applicant(s)

BLAIR ET AL.

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicant's amendments and remarks in Paper No. 7, filed 7/14/03, are acknowledged.

Applicant's arguments, filed 7/14/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The traversal to the restriction requirement is acknowledged. The previous Office Action, mailed 2/13/03, made the restriction requirement FINAL and is hereby maintained.

Claims 1-23 are herein under examination.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-23 is maintained under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. This rejection is maintained and reiterated for reasons of record.

Applicants assert that the claims are definite. This is found unpersuasive as there appear to be vague and indefinite issues as described, *infra*. Applicants make reference to MPEP § 2173.01 that Applicants are their own lexicographers and may use functional language as long as

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the boundaries of the subject matter in the claims are clear. It is true Applicants can be their own lexicographers and should state claims clearly so that the metes and bounds of the claims is understood. It is acknowledged that Applicants make reference to MPEP § 2173.02 which suggests how an Examiner should examine 35 U.S.C. 112, second paragraph, issues.

Claims 1 (lines 8, 15, and 17-20), 5 (line 2), 6 (line 1), 13 (lines 2-4, 11, 18, 20-21, 23-24, and 26), 17 (line 2), 18 (line 2) are vague and indefinite due to the unclarity of citing the abbreviation CPU. Correction is suggested by amending in of the full name in parentheses. Claims 2-4, 7-12, 14-16, and 19-23 are also rejected due to their direct or indirect dependence from claims 1, 6, 13, and 18. This is a standard rejection used whenever an abbreviation is placed into a claim.

Claims 1 (line 12) and 13 (line 15) are vague and indefinite due to the unclarity of citing the abbreviation ID. Correction is suggested by amending in of the full name in parentheses. Claims 2-12 and 14-23 are also rejected due to their direct or indirect dependence from claims 1 and 13. This is a standard rejection used whenever an abbreviation is placed into a claim.

Claims 4 (line 4) and claim 16 (line 4), recite the phrase "efficient structure" which is vague and indefinite. It is unclear what criteria or to what degree one considers the structure to be efficient. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Applicants direct the Examiner to paragraph 68 which they say defines "efficient structure" as "efficient structure, e.g. 2 bits per nucleotide with appropriate encoding, 5 bits per amino acid residue with appropriate encoding, etc.". This is found unpersuasive as this "e.g." is an example, rather than a definition that gives clear metes and bounds of the phrase.

Claims 7 (line 7) and 19 (line 8), recite the word "efficiently encoded representation of alignment" which is vague and indefinite. It is unclear what criteria or to what degree one considers the representation of alignment to be efficiently encoded. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 8-11 and 20-22 are also rejected due to their direct or indirect dependence from claims 7 and 19. Applicants submit that one of skill in the art would clearly understand the meaning of the above-mentioned phrase. This is found unpersuasive as the phrase including the term "efficiently" renders the claim unclear to one of ordinary skill in the art due to the unclarity of the metes and bounds of the word, phrase, and therefore claim.

Claims 8 (line 2), 10 (line 1), 11 (line 2), 21 (line 2), and 22 (line 2) are vague and indefinite due to the unclarity of citing the abbreviation BLAST. Correction is suggested by amending in of the full name in parentheses. This is a standard rejection used whenever an abbreviation is placed into a claim.

Claim 8, lines 1-2, recites the phrase "seed point and sum-set membership" which is vague and indefinite. It is unclear how the Applicants intend this phrase to be defined. Clarification of the meaning of this phrase is requested. Applicants state that one of skill in the art would readily understand the definitions of the terms "seed" (a matching word/string) and "sum" (a part of the scoring when using BLAST) (page 7, third paragraph of Response). This is found unpersuasive as "Basic Local Alignment Search Tool" by Altschul et al. (1990; see prior art reference in 35 U.S.C. § 103 rejection in previous Office Action, mailed 2/13/03) is an article which describes BLAST in detail, but makes no mention of these particular terms.

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Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1, 4, 6-7, 9-10, 12-13, 16, 18-21, and 23 is maintained under 35 U.S.C. 103(a) as being unpatentable over Altschul et al. (1990), in view of Fujimiya et al. (P/N 5,706,498), Anderson et al. (1998), Lincoln et al. (P/N 6,303,297), and Matsumoto et al. (2000). This rejection is maintained and reiterated below for reasons of record.

Applicants state that in a prima facie case of obviousness, three basic criteria must be met: motivation, reasonable expectation of success, and a teaching of all of the claim limitations. This statement is acknowledged. Applicants state that none of these criteria have been met. This is found unpersuasive for the reasons discussed below. Applicants state there is no motivation to modify or combine the references. This is found unpersuasive as a search for more efficient

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means, as described in several of the references (i.e. Fujimiya et al., Matsumoto et al., and Lincoln et al. [see last paragraph of 35 U.S.C. 103 rejection) provides adequate motivation to make improvements to provide rapid and accurate access to the information to gene database retrieval. Applicants argue (p. 8, first paragraph to p. 9, second paragraph) that the motivation differs from that of the present invention. This is found unpersuasive as the motivation to combine references need not be the same motivation or reasons found in the instant invention.

Applicants state there is no reasonable expectation of success to find the Applicants' claimed invention for comparing large datasets obvious in view of the plurality of references which require large datasets or processing them in parallel over a network. This is found unpersuasive as proper motivation was found to combine the limitations stated in the claims. In addition, a proper motivational statement (as provided in the 35 U.S.C. 103 rejection) would cause one of skill in the art to have reasonable expectation of success.

Applicants state there is no disclosure or suggestion of dividing the sequence comparison problems into discrete segments. This is found unpersuasive as Applicants appears to be referring to claim 1, lines 2-5, which under its reasonably broad interpretation is taught by the first six lines of the Altschul et al. prior art paragraph, *infra*. For example the sequence segments may be any length or *certain* ones having a specified range which is reasonably interpreted to mean a subset or division from the other elements. Anderson et al. also refer to a dataset and a choosing (which is reasonably interpreted to cause division) of sequences in p. 351 (col. 1, second paragraph to col. 2) which is also explained in the Anderson et al. prior art paragraph, *infra*.

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Applicants state the interpretation of database and external public databases as "master and slave CPUs" is erroneous. This is found unpersuasive as the Lincoln et al. prior art rejection paragraph, *infra*, explains a method and system of storing and retrieving data from a database and external public databases using an integrated network including CPUs. Since Lincoln et al. explain this database to be stored on a server connected to a network including computers with CPUs, this reasonably suggests the concept of master and slave CPUs.

Altschul et al. (1990) disclose an algorithm named BLAST which performs DNA sequence comparisons on the computer in a variety of contexts, including DNA database searches (page 403, abstract, lines 1 and 5-8). Altschul et al. disclose searching newly sequenced genes (query dataset) to DNA sequence databases (subject dataset) (page 403, col. 1, lines 4-8). Altschul et al. disclose the sequence segments can be of any length (page 404, col. 1, lines 34-36) or certain short sequences thus having a specified range (page 404, col. 2, lines 61-63). Altschul et al. use a list, or index, of all 12-mers in a query sequence in one example (page 405, col. 1, lines 33-35). Altschul et al. disclose a word pair to be a segment pair of fixed length, w , (page 404, col. 2, lines 25-26) and determine the number of 12,500 word combinations by multiplying 50 words by 250 (page 404, col. 2, lines 55-57). Altschul et al. disclose compressing the database by packing 4 nucleotides into a single byte and using a table to delimit the boundaries between adjacent sequences (page 405, col. 1, lines 37-40). Altschul et al. disclose filtering out "uninformative" words or subsequences from the query list which including repeats (page 405, col. 1, lines 61-69). Altschul et al. disclose creating a table of all the hits or comparisons of w -mers in the database (page 405, col. 2, lines 16-19). Altschul et al. disclose

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two gene datasets (page 409, col. 1, lines 9-11) which were run in BLAST using various comparison parameters, such as match score 5, mismatch score -4, and $w=12$ (page 409, col. 2, lines 3-5). Altschul et al. do not determine the communication between master and slave CPUs, loop sequences, store start and stop bounds information of sequences and an efficiently encoded alignment representation, including files with sequence data and metadata, or generate a report.

Fujimiya et al. (P/N 5,706,498) disclose M as the number of elements of the first sequence data and N as the number of elements of the second sequence data (col. 4, lines 8-10). Fujimiya et al. disclose the number of computations as $M*N$ (col. 4, line 27 and col. 6, lines 24-26). Fujimiya et al. disclose computing similarity between sequences and subsequences (col. 4, lines 29-36). Fujimiya et al. disclose a workstation involved in a network as well as a database from a research institution or organization (col. 7, lines 59-67). Fujimiya et al. disclose a transfer of data through the network where information from a gene database is acquired, a homology analysis is performed, and results are retrieved (col. 8, lines 8-18).

Anderson et al. (1998) disclose testing a subset of EMBL database (subject dataset) with seed (query) sequences (page 350, col. 2, lines 48-50) and a test set (query dataset) with various lengths (page 351, col. 1, lines and Table 1). These sequences featured (chosen) lengths within the range of 100 to 1000 bp (page 351, col. 2, lines 3-4). Anderson et al. disclose task definitions which include comparison parameters, such as parameters and scoring matrix (page 351, Table 2); executable elements, such as Smith-Waterman and BLAST algorithms (caption of Table 2, page 351); and data element ID/descriptors, such as the gene name and accession numbers (page 351, Table 2).

Lincoln et al. (P/N 6,303,297) disclose a method and system of storing and retrieving data from a database and external public databases (col. 3, lines 30-37), which the Examiner interprets as master and slave CPUs. The data is edited before entry into the system (col. 3, lines 36-37) and stored as information in database tables (col. 3, lines 41-43). Lincoln et al. disclose the sequence data as well as other annotated biological information can be accessed and stored (col. 15, lines 46-51 and Figure 17). Lincoln et al. disclose that users can store, track, and manipulate the sequences with access to an integrated network, including CPUs (col. 15, lines 51-59). The database is stored at a file server connected to the network, with computers linked to a computer with the internal database, including input and output devices (col. 15, lines 60-67). Lincoln et al. disclose the sequence comparisons performed involve comparing within clustered data sets, within the internal database or with external databases (col. 19, lines 34-37). Lincoln et al. disclose the comparisons are made and match BLAST scores are checked against a threshold (col. 12, lines 42-48). If the threshold is exceeded then the sequence is annotated with the appropriate match information and further comparisons are halted (col. 12, lines 48-51), suggesting that if no threshold is reached then comparisons continue in an iterative or looping manner. Data relating to the comparisons are stored in tables containing information about the quality of sequence matches and other features, including homology, and functional motifs and domains (col. 19, lines 42-54), such as those found in a BLAST report (Figure 6). Figure 6 features index information for both the query and subject (match), line alignments note the start and stop of the sequences, and listed BLAST scores for high-scoring pairs.

Matsumoto et al. disclose DNA sequence compression algorithms for DNA that preprocesses palindrome or repeat sequence which eliminates redundancy (page 43, abstract,

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lines 15-17), packs each DNA sequence into an efficient structure (less than 2 bits per symbol) (abstract, lines 7-8), creates an index, or context tree, with nodes to store information (page 46, lines 1-5), which is compressed in an algorithm known as Context Tree Weighting Method (page 43, abstract, lines 7-8). Matsumoto et al. also disclose other algorithms which expand DNA sequences in size (page 43, abstract, lines 6-7 and page 44, lines 29-31).

Fujimiya et al. state that previous conventional gene database retrieval systems require a large-scale computer having a capacity to perform large volumes of computations, but that such a computer system is not always readily available (col. 8, lines 46-53). Fujimiya et al. discuss the need to make highly accurate homology retrieval with practical processing time (col. 8, lines 56-60). Matsumoto et al. state that database sizes are increasing fast so that there is a need to store and communicate data efficiently (page 43, lines 4-6). Lincoln et al. state the need for a computer-based system to efficiently analyze and compare genetic sequences and corresponding biological data (col. 2, lines 43-47). A skilled artisan in the art would have been motivated to make improvements to a rapid homology retrieval program, such as that stated by Altschul et al. (page 403, abstract, line 1) on various datasets in order to provide faster and more accurate access of the information to users, as stated by Fujimiya et al. (col. 8, lines 46-53) and Matsumoto et al. (page 43, lines 4-6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to test datasets, as stated by Anderson et al. (page 350, col. 2, lines 48-50 and page 351, col. 1, lines and Table 1), containing possible combinations as stated by Fujimiya et al. (col. 4, line 27 and col. 6, lines 24-26), by using a homology retrieval BLAST program, as stated by Altschul et al. (page 403, abstract, line 1), and speeding up the process by compressing files, as stated by Matsumoto et al. (page 43, abstract,

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lines 7-8) and looping the sequences analyzed, as stated by Lincoln et al. (col. 12, lines 48-51), with generated reports which could all be sent over a network of CPUs and databases in order to allow greater, faster, and efficient access to users of the homology information via methods and a computer system (Fujimiya et al., col. 8, lines 56-60 and Matsumoto et al., page 43, lines 4-6) at the time of the invention. Thus, Altschul et al., in view of Fujimiya et al. (P/N 5,706,498), Anderson et al. (1998), Lincoln et al. (P/N 6,303,297), and Matsumoto et al. (2000) motivate the limitations of claims 1, 4, 6-7, 9-10, 12-13, 16, 18-21, and 23.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 10, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER